V. 510(K) SUMMARY

Lapidus Plates

Submitter's name and address:

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Contact person and telephone number

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Authorized Agent in the United States

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Date Summary was prepared:

February 20, 2006

Name of the device:

Proprietary Name:	Lapidus Plate
Common Name:	Plate, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21CFR 888.3030)
Device Product Code:	HRS
Classification Panel:	Orthopedic

Substantial Equivalence:

The **Lapidus Plate** is substantially equivalent to the Acumed Lower Extremity Congruent Bone Plate System, K033639 the Synthes Modular Foot System – 2.7 mm Module, K010321 and the Synthes Modular Foot System, K001941.

Device Description:

The NEWDEAL® Lapidus Plate consists of an osteosynthesis plate designed to bridge the 1st tarsometatarsal joint, available in different sizes, which are implanted using NEWDEAL® locking system fixation screws and washers. The NEWDEAL® locking system includes as many fixation screws as there are threaded lipped sockets on the plate and as many washers as implanted screws. The NEWDEAL® locking system creates a single /screw unit fixed into the bone. The osteosynthesis screws must be driven into the bone through the holes in the plate. The system is locked by means of washers drilled into the threaded lipped socket at the top of each hole, thus blocking each screw head.

Intended Use:

The NEWDEAL Lapidus Plates are intended to be used for bone fixation such as:

- arthrodesis of the 1st metatarsocuneiform joint to reposition and stabilize a metatarsus primus varus,
- Lisfranc arthrodesis
- Mono or bi-cortical osteotomies or fractures near the 1st metatarsocuneiform joint.

Testing and Test Results:

An evaluation of the bending resistance based upon mechanical calculations has demonstrated that the bending behavior of the Lapidus Plates will be greater than predicate devices (Synthes Modular Foot System).

Conclusion

The Newdeal Lapidus Plates are substantially equivalent to commercially marketed devices, the Acumed Lower Extremity Congruent Bone Plate System, K033639 the Synthes Modular Foot System – 2.7 mm Module, K010321 and the Synthes Modular Foot System, K001941.

The Newdeal Lapidus Plates do not raise any new issues of scientific technology, safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

Newdeal SA
c/o Ms. Judith O'Grady, R.N., M.S.N.
Sr. VP, Regulatory Affairs
Integra Lifesciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K060476
Trade/Device Name: Lapidus Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: May 10, 2006
Received: May 11, 2006

Dear Ms. O'Grady:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, M.S.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

IV. Indications for Use

510(k) Number (if known):

Device Name: Lapidus Plates

Indications For Use:
The NEWDEAL Lapidus Plates are intended to be used for bone fixation such as:

- arthrodesis of the 1st metatarsocuneiform joint to reposition and stabilize a metatarsus primus varus,
- Lisfranc arthrodesis
- mono or bi-cortical osteotomies or fractures near the 1st metatarsocuneiform joint.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert Lerner MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060476